a blood bank able to provide all blood components 24 hours a day in both Level I and II. Cross matching shall allow for transfusions within one hour unless some unusual antibody is encountered. Hospitals with Level I units must have radiology services capable of portable radiography, fluoroscopy, computerized tomography scanning, ultrasonography, and nuclear scanning angiography. Diagnostic cardiac and neurologic studies shall be available to both Level I and II unit facilities. A catheterization laboratory or angiography suite must be present in facilities with Level I units. Level I units shall have the capability to provide hemodialysis 24 hours a day.

Equipment/Drugs

There shall be lifesaving therapeutic and monitoring equipment present in Level I and II units. There shall be a complete "code" or "crash" cart available on both Level I and II units. The cart contents should include, but not be limited to, approved medications, a defibrillator/cardioverter, automated blood pressure apparatus devices available on Level I and II units. All equipment shall be of proper size for infants and children. Oxygen tanks are needed for transport and backup for both Level I and II units. There will be additional equipment available to meet the needs of the patient population. Level I units shall have the capability of ventilator support. There must be bedside monitoring in all PICUs with the capability for continuously monitoring heart rate and rhythm, respiratory rate, temperature and one hemodynamic pressure. In level I, units must also have the ability to monitor systemic arterial, central venous, pulmonary arterial and intracranial pressures. The monitors must have alarms with both high and low settings and they must also have both audible and visible capability. There shall be a maintenance and calibration schedule maintained for all monitoring devices.

Pre-hospital Care

PICUs shall be integrated with the Regional EMS system as available. Rapid access to a Poison Control Center is essential. Each PICU shall have or be affiliated with a transport; system and team to assist other hospitals in arranging safe patient transport.

Miscellaneous Requirements

There shall be a quality assurance program in place which reviews quality of care and compares observed and predicted mortality rates for the severity of illness in the population of the PICU. Each Level I PICU shall offer pediatric critical care education for EMS providers, emergency department and transport personnel as well as for the general public. The staff nurses and respiratory therapists must also have Basic Life Support Certification.

Level I PICUs will possess sufficient patient volume, teaching expertise, and research capability to support a fellowship Program in Pediatric Critical Care. Programs providing sub-specialty training in critical care must possess approval by the residency review committee of the accreditation council on graduate medical education. Research is essential for improving our understanding of the pathophysiology affecting vital organ systems. Such knowledge is vital to improve patient care techniques and therapies and thereby decrease morbidity and mortality.

Burn Care Unit

Burn care units are to provide optimal care for patients with burn injuries (both adults and children) from the time of injury through rehabilitation. DHH is adopting the American Burn Association's guidelines which are specified below.

Organizational Structure Documentation of Policies and Procedures

The commitment of the institution's medical and administrative leadership should be documented in a burn center manual with policies specifying the commitment. Policies included should address the institutional relationships, administrative operation, staffing, and programs of the burn center.

The burn unit is a specialized nursing unit that is dedicated to burn care. The use of beds in the burn unit by other medical/surgical services should be governed by a protocol specifying priorities and assuring the availability of specialized burn beds for patients with acute burns when needed.

Relationship to Other Medical Staff

The availability and accessibility of consultation by physicians and surgeons in all specialties relevant to the care of the patient with burns should be documented. An on-call schedule should be established for the most important specialty areas.

Burn Service

An organized burn service should be formally established by the medical staff of the institution. The members of the burn service should be properly certified by the institution. The chief of the burn service should serve as the medical director of the burn center.

Qualifications of the Burn Center Director

The medical director of the burn center should be a licensed, board certified general or plastic surgeon on the active medical staff of the institution with at least 2 years experience in the management of patients in a burn center.

Responsibilities of the Burn Center Director

The medical director will be provided by the institution with the appropriate authority and responsibility to direct and coordinate all medical services to patients admitted to the burn center. The medical director will be responsible for regular communications with physicians and other authorities regarding referred patients, and for appropriate burn center management functions, including quality assurance, liaison with adjacent burn centers, internal and external education programs, and coordination with regional and state EMS programs. The burn center director will designate one or more appropriately certified physicians with at least six months experience in management of the patient with burns to be accessible for administrative and clinical decisions when the director is not available. The burn service director should participate actively in at least 50 cases a year.

Consistency of Protocol and Reporting

The care of the burn center patients accommodated in areas other than the specialized nursing unit should be guided by policies and protocols consistent with those of the burn unit. Similarly, annual statistical reports should encompass care provided both in the burn nursing unit and in other units accommodating burn center patients.

Admission of Census Levels for the Burn Center

The following numbers of patients are deemed appropriate to maintain skill levels and provide reasonable access to specialized burn care. The average daily census of the burn center, including the burn unit and any other areas ommodating patients with acute injuries in the burn service, ould be at least four patients with acute burns. The number of acute burn admissions to the burn center, including the burn unit and any other areas accommodating burn center patients, should exceed 75 annually. Burns identified as usually requiring referral to a burn center (as detailed in the next paragraph) should make up at least 80 percent of the admissions required to meet this standard.

Burn Center Referral Criteria

Burn injuries usually requiring referral to a burn center include the following (questions concerning specific patients can be resolved by consultation with the burn center physician):

1. second and third degree burns greater than 10 percent total body surface area (TBSA) in patients under 10 or over 50 years of age;
2. second and third degree burns greater than 20 percent TBSA in other age groups;
3. second and third degree burns that involve the face, hands, feet, genitalia, perineum, and major joints;
4. third degree burns greater than five percent TBSA in any age group;
5. electrical burns including lightning injury;
6. chemical burns;
7. burn injury with inhalation injury;
8. burn injury in patients with preexisting medical ...sorders that could complicate management, prolong recovery, or affect mortality;
9. any patients with burns and concomitant trauma (for example, fractures) in which the burn injury poses the greatest risk of morbidity or mortality. In such cases, if the trauma poses the greater immediate risk, the patient may be treated initially in a trauma center until stable before being transferred to a burn center. Physician judgment will be necessary in such situations and should be in concert with the regional medical control plan and triage protocols;
10. hospitals without qualified personnel or equipment for the care of children should transfer children with burns to a burn center with these capabilities;
11. burn injury in patients who will require special social/emotional and/or long-term rehabilitative support, including cases involving suspected child abuse, substance abuse, etc.

Medical Personnel

Medical care to burn center patients should be provided by the burn center medical director or other appropriately certified physicians operating with the director's approval and utilizing standard burn center patient care protocols.

Coverage

There should be at least one full-time equivalent surgeon ...olved in the management of patients with burns for each ... annual inpatient admissions to the burn center. This coverage requirement may be met in part by residents.

Surgical Specialty Support

Staff specialists are to be on call and available promptly for consultation in the specialties listed below. The initial response may be provided by residents who are capable of assessing emergency situations in their respective specialties and who can provide any immediately indicated treatment.

The surgical specialties for which staff members are to be on call for are: general, cardiothoracic, neurologic, obstetrics/gynecologic, ophthalmic, oral, orthopedic, otorhinolaryngologic, pediatric, plastic, urologic.

Nonsurgical Specialty Support

Members of the following nonsurgical specialties should be available: anesthesiology, cardiology, gastroenterology, hematology, infectious disease, internal medicine, nephrology, neurology, nutrition, pathology, pediatrics, physiatry, psychiatry, pulmonary, radiology.

Nursing Personnel

One registered nurse (RN) should be administratively responsible for the burn unit. This individual should be a full-time employee with two years of intensive care or equivalent experience and a minimum of 12 months of experience in a burn unit. Education qualifications will be a baccalaureate degree (minimum) and at least six months of management experience.

Staffing Levels

The assigned number of nursing staff hours should be based on a documented patient classification system.

Burn Rehabilitation Therapy

Both physical and occupational therapy should be represented in the burn center staff. The respective roles of physical and occupational therapy should be representative of and consistent with their respective professional training and with licensing laws.

Coverage

Burn rehabilitation therapists may be physical therapists or occupational therapists. They should be licensed or registered in their specific disciplines and should be assigned on a full-time basis to the burn center. Staffing should be based on the combined inpatient and outpatient work load of the burn service. There should be at least one full-time equivalent burn therapist for an average of seven patients, which may represent a combination of both inpatients and outpatients.

Rotation of Personnel

Where either therapy service is provided to the burn center on a rotational basis, rotations must be for at least 3 months and must be filled by therapists who meet the continuing education requirements in burn care as related to their specialty.

Supervision

During their initial rotation, therapists in either discipline should receive regular supervision from individuals who have a minimum of one year of experience in burn treatment.

Other Personnel - Social Worker

A social worker should be assigned permanently to inpatient and outpatient burn care facilities. If assignment is by rotation, such rotations should be at least one year in duration.

Nutrition

A dietitian should be available on a daily basis for

consultation to burn center medical and nursing staff and patients.

Pharmacy

A pharmacist should be available on a daily basis for consultation to burn center medical and nursing staff and patients. This pharmacist should have had a minimum of six months of critical care experience and should be knowledgeable in pharmacokinetics and the special kinetics of patients with burn injuries.

Respiratory Therapy

Respiratory therapists should be available to participate in the assessment and treatment of all burn center patients as needed.

Clinical psychologists and clergy should be assigned permanently to inpatient and outpatient burn care facilities. If assignment is be rotation, such rotations should be at least one year in duration.

The majority of pediatric patients with burns are treated in burn centers with both adult and pediatric patients. Burn centers that treat pediatric patients should have personnel with special interest and expertise in the care and management of children with burns.

Other Services

Protocols governing the involvement of other hospital departments in support of the burn center should be included in the burn center manual. Such departments will include, but not limited to, central supply, emergency, housekeeping, laboratory, pharmacy, public relations, security, and volunteers.

Program for Quality Assurance

The burn center manual will include protocols and policies that support systematic and comprehensive approaches to the care of the patient with burns. These should include triage and resuscitation/stabilization protocols that should be disseminated to health care providers within the burn center service area. A coordinated multidisciplinary plan should be developed for each patient on admission and revised as appropriate during hospitalization with respect to both treatment objectives during hospitalization and postdischarge plans.

Weekly Conference

Conferences should be held at least weekly to review and evaluate the status of each burn center inpatient with representation by each clinical discipline regularly involved in burn center care. The conference should include a review of each patient's progress in recovery, need for surgery, and rehabilitation needs, both physical and psychosocial.

Other Conferences

A documented morbidity/mortality conference should be held at regular intervals consistent with education program requirements. Other conferences of a problem-solving nature should be scheduled with minutes taken to document the responsibility for problem-solving and to record the results of actions taken.

Registry

The burn center will have an internal registry for all inpatients and should participate in an externally based registry.

Audit

The burn center will provide an audit of the previous year's patient care covering at least severity of burn, deaths, incidence of complications, length of hospitalization, and cost of care. Additional audits of any of these or other elements of care will be carried out as a given situation requires.

Participation in EMS System

The burn center will cooperate with the appropriate audit committees of the regional or state EMS system where they exist, by providing patient care data for system management, quality assessment, and operations research, both routinely and in response to special requests, and by participating in local audits of the EMS system.

Other Programs

Education Program

Medical, nursing, and ancillary staff of the burn center will participate in educational programs or activities pertaining to burn care, both at initial orientation and on a planned, organized and coordinated inservice basis. Educational programs should be designed to incorporate the results of problem-solving audits and conferences.

Participants in the hospital's general surgery and other residency programs should have the opportunity to experience a rotation to the burn service.

A formal educational program in burn care shall be required for all nurses, physical therapists, and occupational therapists employed in the burn center with burn care content equivalent to approximately four continuing education units. This educational program will be related to the individual nurse's or therapist's background and level of responsibility in the burn center. Nurse education will be planned and coordinated by the burn unit head nurse or by a member of the hospital nursing staff with equivalent critical care and burn nursing experience.

All professional personnel employed in the burn center will have access to continuing education programs in burn care conducted inside or outside the institution on at least an annual basis. All educational programs should meet the standard of some external organization that provides or approves curriculum or continuing education programs, where such an organization is available.

Rehabilitation Program

The burn center should provide the following rehabilitation services:

1. recreational and educational services during hospitalization for those patients able to utilize them;

2. evaluation of needs and support capabilities of patient's family or other significant persons and cooperative planning with family or other significant persons for patient discharge;

3. documentation of need for and availability and accessibility of community resources to assist in meeting the patient's physical, psychosocial, educational, and vocational needs following discharge. The social worker assigned to the burn unit should coordinate these activities. A clinical psychologist or psychiatrist should be available for consultation as needed;

4. evaluation of each patient's physical, psychological, and vocational status should be done at appropriate intervals

after discharge from the hospital;

5. plans for readmission for medical/surgical treatment for late problems or rehabilitation and reconstruction.

Burn Prevention

A member of the burn center or hospital staff should be assigned to maintain data and develop statistics regarding the causes of injuries sustained by burn center patients. Each burn center system should participate in a public burn awareness program covering prevention and immediate treatment of burn injuries.

Burn Research

Burn center staff should be involved in research related to burn injury that may include, but is not limited to, basic research, clinical research, or health services research.

Configuration and Equipment

The burn unit should contain beds that should be used predominantly for the care of patients with burn injuries or those suffering form other injuries or skin disorders whose treatment requirements are similar to those of patients with burns. Intensive care capability, providing full cardiopulmonary monitoring and respiratory support, should be available for at least four beds in the burn unit. Because of the known susceptibility of burn wounds to infection, an effective means of isolation should be provided for all patients.

Equipment

The following equipment should be available to all patients in the burn unit: weight measurement devices, a system of temperature control in areas where patients' wounds are exposed, oxygen sources with concentration controls, cardiac emergency cart, and backup electrical supply.

The following equipment and supplies should be available in both the hospital emergency department and the burn unit and should be available in sizes and doses appropriate for adult and pediatric patients; airway control and ventilation equipment, including laryngoscope and endotracheal tubes of appropriate sizes; bag mask resuscitator and source of oxygen; bronchoscopes; suction devices; sterile surgical sets; gastric lavage equipment; drugs and related supplies; roentgenographic equipment; Foley catheters; electrocardiograph/oscilloscope/defibrillator; apparatus to establish central venous pressure; and intravenous fluids and administration devises, including intravenous catheters.

Communications with Prehospital Services

There should be a direct communication link between the prehospital system and the burn center. The contact point may be either in the burn unit or in the emergency department.

Renal Dialysis Capability

There should be provision for renal dialysis on a 24-hour basis or a written transfer agreement with an available and accessible dialysis facility in another hospital.

Radiologic Capability

The hospital's radiologic capability should be provided on a 24-hour basis and should include angiography, sonography, nuclear scanning, and computed axial tomography.

Clinical Laboratory Service

The hospital's clinical laboratory service should be available 24 hours a day and should include the following capabilities; routine studies for blood, urine, and other body fluids; blood gases; pH determinations and carboxyhemoglobin; coagulation studies; serum and urine osmolality; microbiologic culture and sensitivity; comprehensive blood bank or access to a community central blood bank; adequate hospital storage facilities; and toxicology screening.

Operating Suites

Operating suites used in burn surgery should contain or have access to the following equipment; operating microscope, thermal control equipment for patients, roentgenographic equipment, dermatomes including mesh dermatones, electrocardiograph/oscillo scope/defibrillator, direct blood pressure arterial line equipment, blood flow rate monitor, in-line blood and intravenous fluid warmers and anesthetic breathing circuit heating humidifiers.

Skin Bank

If a skin bank exists, the physical configuration must conform to the standard of the American Association of Tissue Banks or equivalent. If there is no skin bank, a protocol for procurement and handling of banked skin should exist, if banked skin is used.

Special Areas

A conference room/meeting room, a family room and an adequate exercise area must be available.

Transplants

Transplant services covered under the Medical Assistance Program include but are not limited to heart, liver, kidney and bone marrow transplants for which rates have been established. Rates for other types of transplants will be established as necessary. Transplants must be pre-approved by the department and performed in hospitals that meet the federal criteria required to qualify as a Medicare-designated transplant center including volume requirements for related procedures when applicable. The bureau's health standards section may grant an exception to the qualifying criteria for a hospital whose transplant program was recognized by Medicaid of Louisiana prior to July 1, 1994. These hospitals must operate or participate in a recognized organ procurement program.

As transplants become recognized as non-experimental and covered by Medicare, the department will develop rates and criteria accordingly.

In addition to the above criteria, transplant units must meet the following criteria for recognition by Medicaid for specialty unit reimbursement:

1) must be a member of the (OPTN) Organ Procurement and Transplant Network;

2) must have organ receiving and tissue typing facility (HCFA approved for histocompatibility) or an agreement for such services;

3) must maintain written records tracking mechanism for all grafts and patients including:

a) patient and/or graft loss with reason specified for failure;

b) date of procedure;

c) source of graft;

d) if infections agent involved must have written policy for contacting patients and appropriate governmental officials;

4) must have written criteria for acceptable donors for each type of organ for which transplants are performed;

5) must have adequate ancillary departments and qualified

staff necessary for pre-, intra-, and post-operative care including but not limited to:

a) assessment team;
b) surgical suite;
c) intensive care;
d) radiology;
e) laboratory pathology;
f) infectious disease;
g) dialysis;
h) therapy (rehab);

6) minimum designated transplant staff:

a) transplant surgeon—adopt standards as delineated and updated by the Organ Procurement and Transplant Network;

b) transplant physician—same as above;

c) clinical transplant coordinator:

(1) RN Licensed in Louisiana;

(2) certified by NATCO or in training and certified within 18 months of hire date;

d) transplant social worker;
e) transplant dietician;
f) transplant data coordinator;
g) transplant financial coordinator;

Note: (For 6.a-g above, continuing education is required for continued licensure and certification as applicable.

7) written patient selection criteria and an implementation plan for application of criteria;

8) facility plan, commitment and resources for a program capable of performing the following number of transplants per ar/per organ a minimum of:

a) heart - 12;
b) liver - 12;
c) kidney - 15;

other organs as established per Medicare and/or OPTN. If level falls below the required volume, the hospital will be evaluated by health standards for continued recognition as a transplant center;

9) facility must demonstrate survival rates per organ type per year which meet or exceed the mean survival rates as published annually by the OPTN. (If rates fall below this level, the hospital must supply adequate written documentation for evaluation and justification to Health Standards.)

Hospitals seeking Medicaid reimbursement for high intensity services such as NICU, PICU, burn care and/or transplant must request and submit an application to provider enrollment of the Bureau of Health Services Financing of the Department of Health and Hospitals specifying the service and level of care they are/will be providing. Each applicant must also attest to their compliance with the specified service criteria for each type of service.

Upon receipt of each application, provider enrollment will notify the health standards section of BHSF of DHH to schedule an on-site survey to verify the applicant's compliance with such standards. All applicants will be scheduled within days after receipt of their applications. Annual resurveys will be performed on a 15 percent sample basis throughout the calendar year.

A hospital wishing to change a level of care must submit an application to provider enrollment and an attestation to their compliance with the new levels's requirements. A change in level of care will only be recognized at the beginning of the hospital's subsequent cost reporting period after the health standards section has verified the applicant's compliance via an on-site survey. Therefore, requests should be filed ninety days prior to the beginning of the new cost reporting period.

Interested persons may submit written comments to Thomas D. Collins, Office of the Secretary, Bureau of Health Services Financing, Box 91030, Baton Rouge, LA 70821-9030. He is the person responsible for responding to inquiries regarding this emergency rule and providing information regarding the public hearing. At that time all interested parties will be afforded an opportunity to submit data, views or arguments orally or in writing. Copies of this and all Medicaid rules and regulations are available for review at parish Medicaid offices.

Rose V. Forrest
Secretary

DECLARATION OF EMERGENCY

Department of Public Safety and Corrections
Office of Alcoholic Beverage Control

Beer and Wine Sampling (LAC 55:VII.317)

Under the authority of the Alcoholic Beverage Control Law, particularly R.S. 26:287 and R.S. 26:150(AA), and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B), the Department of Public Safety, Commissioner of the Office of Alcoholic Beverage Control adopts an emergency rule amending the Liquor Credit Regulations, LAC 55:VII.317.D.6.

Emergency rulemaking is necessary since current regulations do not adequately regulate alcoholic beverage sampling on the premises of a licensed retailer. This emergency rule is also necessary as rulemaking has not been completed on the permanent rule.

This emergency rule is effective May 20, 1994 and shall remain in effect for 120 days or until the final rule takes effect through the normal promulgation process, whichever is shortest.

TITLE 55
Part VII. Alcoholic Beverage Control
Chapter 3. Liquor Credit Regulations
§317. Regulation Number IX. Prohibition of Certain Unfair Business Practices in Malt Beverage Industry

* * *

D. Exceptions

* * *

6. Trade Calls

a. Bar spending during trade calls, wherein the beer or wine purchased by a manufacturer or wholesaler for a consumer is consumed on retail licensed premises in the presence of the giver, shall be lawful so long as the state's laws regulating retail establishments such as the legal drinking